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EXAMINER	
LANDAU, SHARMILA GOLLAMUDI	
ART UNIT	**PAPER NUMBER**
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/644,578	LUTZ ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *5 and 12-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments and Remarks filed 9/27/07 is acknowledged. Claims 1-4, 6-11, and 20-23 are directed to the elected invention and species are pending and claims 5 and 12-19 are withdrawn as being directed to a non-elected invention and species.

Election/Restrictions

Applicant argues that claim 5 is readable on the elected species, a mixture of dimethyloldimethylhydantoin and monomethyloldmethylhydantoin as the aldehyde donors. Applicant argues that claim 5 includes the genus methylolhydantoins and mixtures thereof.

This argument is found not to be persuasive since applicant's election is based on the specific mixture of dimethyloldimethylhydantoin and monomethyloldmethylhydantoin as the aldehyde donors. However, as acknowledged by applicant, claim 5 is not directed to the genus methylolhydantoins and not the species monomethyloldmethylhydantoin. Further, claim 5 does not recite dimethyloldimethylhydantoin as a Markush alternative. Therefore, the scope of claim 5 does not encompass a mixture of dimethyloldimethylhydantoin and monomethyloldmethylhydantoin as argued by applicant.

Claim Rejections - 35 USC § 112

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendments of 9/27/07.

Claim Rejections - 35 USC § 102

The rejection of claims 1-2, 7, and 10 under 35 U.S.C. 102(b) as being anticipated by Hahn et al (5,804,203) as evidenced by US 4585656 and 20030207908 is withdrawn in light of the amendments of 9/27/07.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 22 directed to a ratio of (a) to (b) from about 0.05:30 to 30:0.05 does not have support in the specification as originally filed. Page 11 of the instant specification is noted wherein applicant has support of the aldehyde donor to DHA in an amount from 0.05:30 to 30:0.05 but this does not provide support for the aldehyde donor to stabilizer in an amount of about 0.05:30 to 30:0.05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 7, 10, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al (5,804,203) in view of Dodd et al (2002/0176879).

Hahn et al disclose a composition comprising .05-.10% disodium EDTA; 0.2-0.30 imidazolidinyl urea (aldehyde donor); 0.1-0.30 methylparaben; and 0.05-0.2% sodium dehydroacetate, among other ingredients. See example 9.

Hahn does not teach the instant dimethyloldimethylhydantoin ("DMDMH"), a dimethylhydantoin derivative.

Dodd teaches imidazolidone compounds include instant DMDMH (0.005-0.2%) and imidazolidinyl urea and mixtures may be used. see 0179-184.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hahn et al and Dodd and utilize a mixture of imidazolidone compounds (aldehyde donor) including the combination of instant DMDMD and urea. One would have been motivated to do so since Dodd teaches mixtures of imidazolidinedione compounds such as DMDMH and urea for use as preservatives. It is noted that although the prior art does not explicitly teach DMDMH as a stabilizer, DMDMH will function in the same manner since the prior art and the instant claims utilize the same weight percent.

Response to Arguments

Applicant argues that neither Hahn nor Dodd teach or suggest s combination of the (a), (b), and (c) as amended.

Applicant's arguments filed 9/27/07 have been fully considered but they are not persuasive. The examiner points out that the instant combination comprises (a) imidazolidinyl urea, (b) DMDMH, a dimethylhydantoin derivative, and sodium dehydroacetate.

Applicant argues that the instant invention is unexpected as demonstrated in the instant specification.

The examiner notes the Tables in the instant specification. However, the following is noted with regard to the purported unexpected results: Firstly, it is noted that the instant rejection is made on the premise that Hahn is only deficient in the teaching of the component (b). Therefore, demonstrating the unexpectedness of the addition of DHA is not persuasive since the prior art teaches DHA. Further, the examiner notes that instant specification demonstrates a single example comprising 0.075% DHA and 0.25% Glydant 2000 (a 70% solution of hydantoin species including about 36% dimethyloldimethylhydantoin, about 29% monomethyloldimethylhydantoin, and about 5% dimethylhydantoin) has a synergistic effect compared to DHA and Glydant alone. However, the instant claims are not commensurate in scope. For instance, the instant claims do not recite any weight percent of any of the components. It is unclear if the same results would be yielded using different weight percents. Additionally, it is noted that Table 4 utilizes the elected species of aldehyde donor and stabilizer to provide the synergistic results; however the claims are not directed to the species utilized in Table 4. Therefore, arguments of the unexpectedness of the instant invention is not found to be persuasive.

Claims 1-4, 6-11, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothenburger et al (6,121,302) in view Willingham (5,424,324).

Rothenburger et al teach a highly stable formulation having broad-spectrum preservative properties. The formulation is an admixture of dialkanol-substituted dimethyhydantoin, one or more isothiazolone compounds, a hydantoin stabilizer, and a hydroxyl solvent. The formulation has a free formaldehyde content of less than 0.2% and is beneficial for preserving various aqueous compositions, including household and industrial products, and especially personal care products, which require a less acidic pH range than in which isothiazolone is stable in the presence of cationic salts. See abstract. Rothenburger teaches isothiazolone is highly toxic and very unstable under most circumstances, such as when present in water or other reactive molecule. To make the compound stable large amounts of cationic salts are added and the isothiazolone is diluted (usually to about 14% or less). While under these conditions, isothiazolone is stable at room temperature at low pH (from 1-4). During storage and manufacturing conditions the temperature and pH may increase causing isothiazolone to become unstable. While highly useful for controlling bacteria, fungi and other contaminating microbes in end-use products, isothiazolone's instability under less than ideal conditions results in a marked loss of activity. Thus, it would be advantageous to provide a preservative system that contains isothiazolone, which is stable at a broad range of temperature and pH.

The stable composition contains 20 to 95 wt % of a formaldehyde donor, 0.02 to 90 wt % of an isothiazolone, 1 to 30 wt % of an alkyl hydantoin stabilizer and up to 60 wt % of a hydroxyl solvent. See claim 3. The formaldehyde donor is a 1,3-dimethylol-5,5-dimethylhydantoin, 1-methylol-5,5-dimethylhydantoin, 3-methylol-5,5-dimethylhydantoin or 1-methylol-3-methyloloxymethylene-5,5-dimethylhydantoin, or *mixtures thereof.* See claim 4. The stabilizer is 5,5-dimethyl hydantoin.

Rothenburger does not teach dehydroacetic acid in the composition.

Willingham teaches the use of carbonyl stabilizers for 3-isothiazoles. The formulation has a broad spectrum preservative. See column 3, lines 25-35. Willingham teaches some carbonyl compounds are known to have microbiocidal activity, although their efficacy as stabilizers of isothiazolones has not previously been appreciated. Such compounds are particularly desirable to use as stabilizers; examples are acrolein, benzoic acid, sorbic acid, dehydroacetic acid, glycolic acid and citric acid. The formulation comprises preferably 0.01-20% of the carbonyl compound. See column 4, lines 40-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings of Rothenburger and Willingham and further utilize dehydroacetic acid in the composition. One would have been motivated to do so since Willingham teaches dehydroacetic acid not only has a stabilizing effect on isothiazolones but also is known to have microbiocidal activity. Therefore, it would have been obvious for a skilled artisan to utilize dehydroacetic acid for its additive effect of further enhancing stability of isothiazole and increase the microbiocidal activity of the composition.

Regarding claim 22, the manipulation of the amount of (a) to (b) is considered prima facie obvious since the prior art provides the general concentrations.

Response to Arguments

Applicant argues that both Rothenburger and Willingham relate to preservative formulations containing isothiazolones. Applicant argues that the present invention does not relate to isothiazolones and does not require an isothiazolone stabilizer. Therefore, applicant argues that one of ordinary skill in the art would not have been motivated to produce a

combination of the antimicrobial composition as claimed (a combination of an aldehyde donor, a stabilizer selected from dimethylhydantoin, urea, and derivatives thereof; a dehydroacetic acid or salt thereof) and an isothiazolone because of the above shortcomings known in the art.

Applicant's arguments filed 9/27/07 have been fully considered but they are not persuasive. The examiner points out that the instant claims are recite "comprising" claim language, which is open-ended claim language and does not exclude additional, unrecited elements. See MPEP 2111.03. Thus, the instant invention does not exclude isothiazolone as argued by applicant.

Applicant argues that the instant invention is unexpected as demonstrated in the instant specification.

The examiner notes the Tables in the instant specification. However, the following is noted with regard to the purported unexpected results: The instant specification demonstrates a single example comprising 0.075% DHA and 0.25% Glydant 2000 (a 70% solution of hydantoin species including about 36% dimethyloldimethylhydantoin, about 29% monomethyloldimethylhydantoin, and about 5% dimethylhydantoin) has a synergistic effect compared to DHA and Glydant alone. However, the instant claims are not commensurate in scope. For instance, the instant claims do not recite any weight percent of any of the components. It is unclear if the same results would be yielded using different weight percents. Further, it is noted that Table 4 utilizes the elected species of aldehyde donor and stabilizer to provide the synergistic results; however the claims are not directed to the species utilized in Table 4. Therefore, arguments of the unexpectedness of the instant invention is not found to be persuasive.

Claims 1-4, 6-11, 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farina et al (5,405,862) in view Trinh et al (6,682,694).

Farina teaches a preservative composition comprising 20-40% of dimethyloldimethylhydantoin, monomethyloldimethylhydantoin, and dimethylhydantoin having less than 0.1% by weight of free formaldehyde based upon 100% of total composition, useful in biocidal effective amounts in industrial or personal care products. See claim 1.

Farina does not teach dehydroacetic acid in the composition.

Trinh teaches a preservative composition including imidazolidinedione compounds such DMDMH for it effective against bacteria. Trinh further teaches the use of DHA in an amount of 0.005-0.2% as a broad spectrum preservative. Trinh teaches the preservatives can be used in mixtures in order to control a broad range of microorganisms.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Farina and Trinh and further utilize DHA in Farina's composition. One would have been motivated to do so with a reasonable expectation of success since Trinh teaches mixtures of preservative may be utilized to control a broad range of microorganisms. Further, Trinh teaches imidazolidinedione compounds kill bacteria whereas DHA is a board spectrum preservative. Thus, a skilled artisan would have been motivated to further add DHA for its additive effect.

Regarding claim 22, the manipulation of the amount of (a) to (b) is considered prima facie obvious since the prior art provides the general concentrations.

Regarding, applicant's synergistic effective shown in specification, the examiner notes the following: The instant specification demonstrates a single example comprising 0.075% DHA

and 0.25% Glydant 2000 (a 70% solution of hydantoin species including about 36% dimethyloldimethylhydantoin, about 29% monomethyloldimethylhydantoin, and about 5% dimethylhydantoin) has a synergistic effect compared to DHA and Glydant alone. However, the instant claims are not commensurate in scope. For instance, the instant claims do not recite any weight percent of any of the components. It is unclear if the same results would be yielded using different weight percents. Further, it is noted that Table 4 utilizes the elected species of aldehyde donor and stabilizer to provide the synergistic results; however the claims are not directed to the species utilized in Table 4.

Conclusion

All the claims are rejected at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616

SGL